Appl. No. 10/688,539 Atty. Docket No. 32328US02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:
Joel S. Echols, et al.	: Confirmation No. 1150
Appl. No.: 10/688,539	: Group Art Unit: 1615
Filed: October 17, 2003	: Examiner: Kishore, Gollamudi S.

For THREE LAYER ARTIFICAL TEAR FORMULATION

REPLY BRIEF

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
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S I R:

Under the provisions of 37 CFR § 41.41, this Reply Brief is being filed in response to the Examiner's Answer mailed on January 7, 2009 in connection with the above-identified application.

Claims 1-6 are pending in the application. Claims 1-6 stand finally rejected by the Examiner as set forth in the Office Action dated January 22, 2008. Claims 7-21 have been cancelled. No claim stands withdrawn or allowed.

ARGUMENT

1. Response to Examiner's comments regarding the rejection of claims 1-6 under 35 U.S.C. § 112, second paragraph

The Examiner states in the Examiner's Answer that appellant's arguments regarding the rejection under 35 U.S.C. § 112, second paragraph are not persuasive with respect to claim 1. Appellant respectfully disagrees and contends that claim 1 is definite for the reasons set forth in the Appeal Brief. Furthermore, appellant submits that claim 5, which recites that the hydrophilic polymer of claim 1 is polyvinyl pyrrolidone, is clearly definite. In reciting that the hydrophilic polymer is polyvinyl pyrrolidone, claim 5 removes any possible confusion between this hydrophilic polymer and the polyvinyl acetate and polyvinyl alcohol recited in claim 1. The Examiner has not specifically addressed this issue in the Examiner's Answer or provided any reasoning as to why claim 5 would be indefinite.

2. Response to Examiner's comments regarding the rejection of claims 1-6 under 35 U.S.C. § 103(a) over Suzuki et al in combination with Guy et al and Holly

In the Examiner's Answer, the Examiner asserts that appellant's arguments in the Appeal Brief are not persuasive. One argument made on page 6 of the Examiner's Answer is that "With regard to Appellant's arguments that Suzuki does not teach polyvinyl alcohol and polyvinyl pyrrolidone together, the Examiner points out that Suzuki on col. 6, line 64 teaches that these are thickeners and it is within the skill of the art to combine two thickeners to achieve a desirable thickness with the phospholipid of Suzuki." However, there is no teaching in Suzuki et al, or any of the other prior art of record, that a *combination* of polyvinyl alcohol and polyvinyl pyrrolidone would produce a desirable thickness. Suzuki et al only discloses that polyvinyl alcohol and polyvinyl

pyrrolidone are two of a number of possible thickeners. There is nothing to lead one of ordinary skill in the art to combine polyvinyl alcohol and polyvinyl pyrrolidone to achieve a desirable thickness or otherwise improve thickness. The Examiner goes on to state that "the combination of all three polymers is taught by Holly," but this is not the basis for rejecting the claims as set forth in the Office Action of January 22, 2008 or in the Grounds of Rejection section of the Examiner's Answer.

Appellant has argued in the Appeal Brief that it would not have been obvious to add polyvinyl acetate to the polyvinyl alcohol already present in the Suzuki et al composition in view of the teaching in Holly. On pages 7 and 8 of the Examiner's Answer, the Examiner states that this argument is not persuasive, arguing that it would have been obvious to use the teachings of Suzuki et al and Holly together because both references involve treating inflammation. Holly teaches an ophthalmic solution for the treatment of dry eye and does identify "inflammatory reaction" as one of a number of symptoms of dry eye. Therefore, it seems reasonable to conclude that the solution taught by Holly would reduce inflammation caused by dry eye. However, Holly clearly teaches treating dye eye (and hence inflammation) by improving tear film stability. In contrast, Suzuki et al discloses treating inflammation by introducing drugs exhibiting strong anti-inflammatory action. Suzuki et al and Holly thus treat inflammation with fundamentally different approaches, and Suzuki et al does not contemplate improving tear film stability. Accordingly, one of ordinary skill in the art would not be motivated to add polyvinyl acetate to the polyvinyl alcohol of the Suzuki et al composition because there is no suggestion in the prior art of record that lowering surface tension of the Suzuki et al composition will improve the ability to dispense the anti-inflammatory drugs.

The Examiner cites *Ex parte Obiaya,* 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985) as support for the assertion that appellant's argument is not

persuasive. However, appellant respectfully submits that the Examiner misunderstands the primary point of appellant's argument. The claimed invention in the *Obiaya* case related to a sensor that included a labyrinth heater, and the prior art apparently showed similar sensors that included labyrinth heaters. The appellant in *Obiaya* noted that the labyrinth heater of the claimed invention provided a shorter response time, while the labyrinth heaters of the prior art were used to maintain the samples at a uniform temperature. The Board in *Obiaya* held that this difference could not be the basis for patentability. The appellant's argument with respect to combining Suzuki et al and Holly is not based on the *appellant's invention* comprising an advantage not recognized by the prior art. Instead, appellant is arguing that it would not have been obvious to modify Suzuki et al with the teaching of Holly because Holly teaches mixing polyvinyl acetate and polyvinyl alcohol in order to lower surface tension, but there is no reason why one of ordinary skill in the art would want to lower surface tension in the Suzuki et al composition. Nothing in the prior art suggests that there would be any benefit to lowering the surface tension in Suzuki et al composition. The holding in *Obiaya* is thus not relevant to this argument.

The Examiner contends on pages 8 and 9 that appellant's argument that the composition of claim 1 yields more than predictable results is not persuasive. Specifically, the Examiner states the "argument is not persuasive since Holly's compositions for the treatment of dry-eye syndrome contains all three polymers. Instant specification provides no comparative data with polymer combination with and without phospholipids." Appellant respectfully submits that this statement does not refute the contention that the composition of claim 1 yields more than predictable results. The fact that the Holly reference discloses the three polymers has no bearing on whether claim 1 does or does not yield predictable results. There is simply nothing in the prior art to suggest that

the combination of elements recited in claim 1 would have predictably replicated all three layers of a normal human tear film.

Regarding claim 2 and appellant's argument that the finished composition of Suzuki et al does not contain ethanol, the Examiner states on page 9 of the Examiner's Answer that the appellant has not shown any criticality of the presence of ethanol and the claim does not even recite any specific amounts of ethanol. Appellant respectfully submits that the alleged lack of criticality of ethanol should not have any bearing on the obviousness of claim 2. Appellant knows of no requirement under U.S. patent law that requires an applicant to show the criticality of a claim element. MPEP § 2144.05 does state that applicants "can rebut a *prima facie* case of obviousness based on overlapping ranges by showing the criticality of the claimed range." However, in this case, there is no *prima facie* case of obviousness based on overlapping ranges because the prior art does not teach a composition including ethanol. Appellant submits that the finished composition of Suzuki et al does not contain any ethanol because any ethanol used is the preparation of the emulsion is distilled off. See column 7, lines 44-46 of Suzuki et al. Furthermore, an applicant should not be required to specify a specific amount of a claimed element when the prior art does not disclose that particular element. Regarding the teaching in Suzuki et al of distilling of ethanol, the Examiner states "it is unclear from the reference whether the ethanol is completely removed." Appellant respectfully disagrees. Lines 37-46 in column 7 of Suzuki et al describe emulsifying adjuvants and one of the anti-inflammatory drugs (FLM, CB and CP) in a solvent such as hexane or ethanol, "followed by distilling off the solvent under reduced pressure to thus form a thin film of the lipid." There is nothing to suggest anything but the complete removal of the solvent.

Regarding claim 6, the Examiner states on page 10 of the Examiner's Answer that Examples 1-3 of Holly test the claimed amounts of

the polymers and Suzuki et al teaches that the amount of phospholipid can be varied. However, appellant respectfully submits that this still fails to render obvious the concentration levels set forth in claim 6.

3. Response to Examiner's comments regarding the rejection of claims 1-6 under 35 U.S.C. § 103(a) over Suzuki et al in combination with Guy et al and further in view of appellant's statements of prior art

Appellant respectfully disagrees with the Examiner's contention it would have been obvious to use Amisol™ with the teachings of Suzuki et al, Holly and Guy et al for the reasons set forth in the Appeal Brief.

Conclusion

Appellant has shown, in the Appeal Brief and this Reply Brief, the rejections under 35 U.S.C. 112, second paragraph, and 35 U.S.C. 103(a) to be in error. Therefore, the Board of Patent Appeals and Interferences is respectfully requested to reverse of the rejections of claims 1-6 and to hold all the claims to be allowable.

Respectfully submitted,

March 4, 2009
Date

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